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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,596	01/21/2004	Wilfred Wayne Lautt	14217.1USC1	4255
23552	7590	09/22/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			DELACROIX MUIRHEI, CYBILLE	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/761,596	Applicant(s) LAUTT, WILFRED WAYNE	
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 9-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Detailed Action***

The following is responsive to the preliminary amendment received Jan. 21, 2004.

Claims 1-8 are cancelled. New claims 9-13 are added.

Claims 9-13 are presented for prosecution on the merits.

***Information Disclosure Statement(s)***

Applicant's Information Disclosure Statement received Jan. 21, 2004 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

***Claim Objection(s)***

1. Claim 11 is objected to because of the following informalities: in claim 11, line 3, before "symptoms", the term "the" should be deleted. Appropriate correction is required.

***Claim Rejection(s)—35 USC 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Klokke-Bethke et al., 5,370,862 or Veronesi et al., 5,580,576 (already of record).

Klokke-Bethke et al. disclose pharmaceutical aerosol sprays containing effective amounts of the nitric oxide agonist, nitroglycerin. Please see the abstract; claim 1.

Veronesi et al. disclose pharmaceutically/storage stable, water resistant formulations comprising nicorandil (a nitric oxide agonist) and pharmaceutically acceptable excipients. Please see the abstract; claim 1.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claim 9 is rejected under 35 U.S.C. 102(e) as being anticipated by Adams et al., 6,165,975 (already of record).

Adams et al. teach pharmaceutical compositions comprising effective amounts of either sodium nitroprusside, 3-morpholinosydnonimine, molsidomine or S-nitroso-N-acetyl penicillamine (SNAP) and a pharmaceutically acceptable carrier. Please see the abstract; col. 7, lines 33-47; col. 15, lines 1-67.

4. Claim 9 is rejected under 35 U.S.C. 102(e) as being anticipated by Papandreou et al., 6,171,232 (already of record).

Papandreou et al. teach that sodium prusside is a generally approved nitric oxide donor pharmaceutical. Furthermore, other known nitric oxide pharmaceuticals include sodium nitrite and the sydnonimines. Please see col. 6, lines 45-55.

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5. Claim 9 is rejected under 35 U.S.C. 102(e) as being anticipated by Salzman et al., 5,958,427 (already of record).

Salzman et al. teach pharmaceutical compositions containing effective amounts of nitric oxide donor compounds. Please see the abstract; col. 2-6.

With respect to the claimed intended uses of the compositions, i.e. to cause an increase in nitric oxide in the liver or to increase insulin sensitivity, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the Examiner respectfully submits that the prior art nitric oxide donor and nitric oxide agonist compositions are capable of performing the claimed intended uses.

Additionally, concerning the limitation "structurally modified to preferentially release nitric oxide in the liver", the Examiner notes that at page 8, lines 10-15 of the specification, the limitation "nitric oxide donors and agonists" is described as encompassing a number of compounds such as SIN-1, SNAP, sodium nitrite and nitroprusside. The Examiner respectfully submits that although the references don't specifically disclose that the nitric oxide donors or agonists are "structurally adapted to preferentially release nitric oxide in the liver", the references do disclose compositions containing compounds (nitroglycerin, nicorandil, SNAP, sodium nitroprusside, etc.) that

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are encompassed by the claims. Therefore, the Examiner submits that the prior art of record anticipates Applicant's claimed compositions.

***Claim Rejection(s)—35 USC 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. and Papandreou et al. and Salzman et al. and Klokke-Bethke et al. and Veronesi et al, all supra.

Said references as applied above.

However, these references do not specifically disclose formulating the compositions into a kit with instructional material as claimed. However, the court in In re Gulack states "where printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." Please see In re Ngai et al., 03-1524 (CAFC 2004) (citing In re Gulack,

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217 USPQ 401 (CAFC 1983)). In this case, the instructional material is not functionally related to the nitric oxide donor or agonist compositions because these compositions can function as an active effective drug even in the absence of the instructional material. Therefore, following the rationale in Ngai and Gulack, one can conclude that the instructional material does not patentably distinguish the claimed compositions over the prior art. Finally, the instructional material describing instruction for using the nitric oxide donor or agonist compositions relates to intended use and does not further limit or define the overall pharmaceutical compositions.

### ***Conclusion***

Claims 9-13 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

CDM

Sept. 20, 2004



Cybille Delacroix-Muirheid  
Patent Examiner Group 1600